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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,601

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Yoshiharu Sato

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EXAMINER

KAFIMOSAVI, HOSEIN

ART UNIT

PAPER NUMBER

4132

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,601	<b>Applicant(s)</b> SATO, YOSHIHARU	
	<b>Examiner</b> HOSEIN KAFIMOSAVI	<b>Art Unit</b> 4132	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/29/2005</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear how the opaque region is between the sample liquid introduction port and window because the specification discloses that the opaque region (layer) is located above the transparent layer of the cover (Pg.8, lines 18-21). Applicant is asked to clarify. For the purpose of examination the analytical tool is simply interpreted to contain an opaque region.

The term "thin film" in claim 9 is a relative term which renders the claim indefinite. The term "thin film" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "high contrast" in claim 11 is a relative term which renders the claim indefinite. The term "high contrast" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 6, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Crismore et al (5,997,817).

As to claim 1, Crismore discloses an analytical tool comprising a sample liquid introduction port (20), a capillary, and a window (18), and also an opaque region (27) (Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 27-29 and lines 61-64).

As to claim 2, Crismore discloses the analytical tool above, further comprising a substrate (1), a cover (13) bonded to the substrate and defining the capillary together with the substrate, and a working electrode (5) and a counter electrode (6) which are formed on the substrate and which include respective exposed portions facing interior of capillary, wherein at least part of the window is formed at a region which avoids a position directly above the exposed portions (Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59).

As to claim 6, Crismore discloses the analytical tool above, further comprising a substrate (1), a cover (13) bonded to the substrate and defining the capillary together with the substrate, wherein the window (18) is provided by forming a transparent portion

in the cover and forming an opaque portion (27) around the transparent portion (Fig. 1 and 5; Column 8, lines 27-29).

As to claim 10, Crismor discloses the analytical tool above wherein the cover (13) includes an opaque member (27) with an opening and a transparent member (18) embedded in the opening; and wherein the window is provided by the transparent member (Fig. 1 and 5; Column 8, lines 27-29).

As to claim 11, Crismor discloses the analytical tool above, wherein the opaque region (27) has a color which presents a high contrast with a color of the sample liquid (Column 8, lines 27-29).

As to claim 12, Crismor discloses the analytical tool above, wherein the sample liquid is blood or urine (Column 9, lines 30-34).

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lea (US 6,403,384).

As to claims 1, Lea discloses an analytical tool comprising a sample liquid introduction port (16), a capillary (14), and a window (10), and also an opaque region (32) (Fig. 1; Column 12, lines 62-67; Column 13, lines 53-55).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 4132

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore et al (US 5,997,817) as applied to claim 1 above, and further in view of Lea (US 6,403,384).

As to claim 7, Crismore discloses an analytical tool comprising a substrate (1), a cover (13) bonded to the substrate and defining the capillary together with the substrate (Fig.1; Column 4, lines 42-45). However, Crismore does not disclose that the cover comprises a transparent member, and an opaque layer with an opening on a surface of the transparent member; wherein the window is defined by the opening.

Lea discloses an analytical tool comprising a substrate (12) and a cover (10 and 32) bonded to the substrate and defining a capillary (14) together with the substrate, wherein the cover comprises a transparent member (10), and an opaque layer (32) with an opening on a surface of the transparent member; wherein the window is defined by the opening (36,38,40) (Fig. 1; Column 12, lines 63-65; Column 13, lines 33-34 and 53-60).

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the cover of Crismore to comprise a transparent member and an opaque layer with an opening on the surface of the transparent member; wherein a window is defined by the opening as taught by Lea, because it would allow simple and fast assembly and production of the invention.

As to claim 8, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113). Crismore as modified in view of Lea, discloses the analytical tool above, wherein the opaque layer (32) is provided by a film directly on the surface of the transparent member (10) (Fig. 1; Column 13, lines 53-60).

As to claim 9, Crismore as modified in view of Lea, discloses the analytical tool above, wherein the opaque layer (32) comprises a thin layer bonded to the surface of the transparent member (10) (Fig. 2A; Column 13, lines 53-55).

9. Claims 3-5, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore et al (US 5,997,817) as applied to claim 1 above, and further in view of Grate et al (US 2003/0095897).

As to claim 3, Crismor discloses the analytical tool above, further comprising a substrate (1), a cover (13) bonded to the substrate and defining the capillary together

with the substrate, and a working electrode (5) and a counter electrode (6) which are formed on the substrate and which include respective exposed portions facing interior of capillary, wherein at least part of the window is formed at a region which avoids a position directly above the exposed portions (Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59). However, Crismore does not disclose that the entirety of the window is formed at a region which avoids a position directly above the exposed portions.

Grate teaches that a capillary or fluid transport pathway that comprise a window or transparent/translucent material can be covered or replaced with an opaque material in order to prevent exposure of light to sensitive reagents used in chemical and optical analysis ([0083]).

It would have been obvious to one with ordinary skill in the art at the time of the invention that the window of Crismore can be covered or replaced by an opaque layer directly above the exposed portions in certain positions as taught by Grate, so that the entirety of the window of Crismore is formed at a region which avoids a position directly above the exposed portions of the electrode for the reason that the biosensor can be applicable with reagents placed on the electrodes that are light sensitive and require protection against light or other electromagnetic radiation (Crismore at Fig.1; Column 3, lines 1-2; Column 8, lines 55-59; Grate at [0083]).

As to claim 4, Crismore as modified by Grate, discloses the analytical tool above, further comprising an air vent (4), wherein the window (18) is (covered by an opaque region leaving exposed the portion) provided between the air vent and a downstream



point of the exposed portions in a flow direction of the sample liquid (Crismore at Fig.1; Column 3, lines 1-2; Column 8, lines 55-59; Grate at [0083]).

As to claim 5, Crismore as modified by Grate, discloses the analytical tool above, wherein the window (18) includes a (cover by an opaque region leaving exposed) most upstream point which corresponds to or generally corresponds to a most downstream point of the downstream one of the exposed portions in a thickness direction of the substrate (Crismore at Fig.1; Column 3, lines 1-2; Column 8, lines 55-59; Grate at [0083]).

10. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore (US 5,997,817) as applied to claim 1 above, and further in view of Grate (US 2003/0095897).

As to claim 13, Crismor discloses the analytical tool above, further comprising a substrate (1), a cover (13) bonded to the substrate and defining the capillary together with the substrate, and a working electrode (5) and a counter electrode (6) which are formed on the substrate and which include respective exposed portions facing interior of capillary, wherein at least part of the window is formed at a region which avoids a position directly above the exposed portions (Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59). However, Crismore does not disclose that the analytical tool above further comprises an additional window.

Grate teaches that a capillary or fluid transport pathway that comprise a window or transparent/translucent material can be covered or replaced with an opaque material

in order to prevent exposure of light to sensitive reagents used in chemical and optical analysis ([0083]).

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the window of Crismore be covered or replaced directly above the exposed portions by an opaque layer as taught by Grate, so that the single window is separated into two windows comprising an additional window, one positioned near the introduction port and the other positioned after the exposed portions of the electrodes, for the purpose of having visual confirmation that sample has entered the capillary and that the exposed portions of the electrodes are fully covered which provides safeguard against erroneous test results due to undetected under dosing of the test strip (Crismore at Fig.1; Column 3, lines 1-2; Column 8, lines 55-64; Grate at [0083]).

As to claim 14, Crismore as modified by Grate, discloses the analytical tool above, further comprising a working electrode (5) and a counter electrode (6) which are formed on the substrate and which include respective exposed portions facing interior of capillary, wherein at least part of the additional window is formed at a region which avoids a position directly above the exposed portions (Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59).

As to claim 15, Crismore as modified by Grate, discloses the analytical tool above, wherein the entirety of the additional window is formed at a region which avoids a position directly above the exposed portions (Crismore at Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59; Grate at [0083]).

As to claim 16, Crismore as modified by Grate, discloses the analytical tool above, wherein the additional window is provided between the sample liquid introduction port (20) and an upstream one of the exposed portions in a flow direction to the sample liquid (Crismore at Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59; Grate at [0083]).

As to claim 17, Crismore as modified by Grate, discloses the analytical tool above, wherein the window the additional window is provided adjacent to the sample liquid introduction port (20) (Crismore at Fig. 1 and 4; Column 4, lines 42-45; Column 8, lines 55-59; Grate at [0083]).

#### ***Contacts/Correspondence Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOSEIN KAFIMOSAVI whose telephone number is (571)270-5271. The examiner can normally be reached on Mon - Fri, 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jessica Ward can be reached on (571) 272-1223. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4132

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. K./

Examiner, Art Unit 4132

/Jessica L. Ward/

Supervisory Patent Examiner, Art Unit 4132